

CROSNER LEGAL, P.C.
Zachary M. Crosner (SBN 272295)
Chad A. Saunders (SBN 257810)
Craig W. Straub (SBN 249032)
9440 Santa Monica Blvd. Suite 301
Beverly Hills, CA 90210
Tel: (866) 276-7637
Fax: (310) 510-6429
zach@crosnerlegal.com
chad@crosnerlegal.com
craig@crosnerlegal.com

Attorneys for Plaintiff

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

NIKOLAS CHAPLIN, individually and on behalf of all others similarly situated,

Plaintiff,

V.

WALMART INC.

Defendant.

Case No.: 3:23-cv-00878-WHO

FIRST AMENDED CLASS ACTION COMPLAINT

Judge: Honorable William H. Orrick

Complaint filed: January 9, 2023
Trial date: Not yet set

JURY TRIAL DEMANDED

1 Plaintiff Nikolas Chaplin (“Plaintiff”) brings this action against Defendant Walmart Inc.
 2 (“Defendant” or “Walmart”), individually and on behalf of all others similarly situated, and alleges
 3 upon personal knowledge as to Plaintiff’s acts and experiences, and, as to all other matters, upon
 4 information and belief, including investigation conducted by Plaintiff’s attorneys.

5 **NATURE OF THE ACTION**

6 1. This is a consumer protection action that seeks to remedy the unlawful and deceptive,
 7 business practices of Defendant with respect to the marketing and sales of its Parent’s Choice Gripe
 8 Water products (“Parent’s Choice Gripe Water” or “Product(s)”).

9 2. Defendant distributes, markets, and sells a Product named “Parent’s Choice Gripe
 10 Water” as an effective remedy for the symptoms associated with colic in newborn babies and infants.

11 3. Gripe water has been sold to unwitting parents as a treatment for colicky infants for
 12 over a century. It is considered a natural “folk” or “alternative” remedy. From a science-based
 13 standpoint, “alternative” medicine is a misnomer. When the clinical evidence demonstrates that an
 14 intervention is effective, it becomes a part of accepted medicine. Yet many “alternative,” and natural
 15 “folk” treatments are sold in the absence of evidence and when the scientific evidence shows
 16 otherwise. Defendant takes advantage of this misconception by placing the words “Gripe Water” on
 17 the front of the Parent’s Choice Gripe Water packaging.

18 4. None of the ingredients in Parent’s Choice Gripe Water provide relief from stomach
 19 discomfort, gassiness, or any of the other symptoms of colic. Scientific studies have found that gripe
 20 water is ineffective for treating colic in newborns and may in fact disrupt the digestive system of
 21 infants and newborns. No respected medical practitioner recommends the use of herbal remedies or
 22 gripe water for use in colicky infants. Defendant is peddling snake oil at the expense of desperate
 23 consumers.

24 5. Walmart’s Gripe Water only disrupts a newborn’s/infant’s digestive system. The
 25 Product contains sodium bicarbonate which is commonly known as baking soda. Numerous
 26 scientific publications warn that the ingredient should not be given to infants because it disrupts the
 27 digestive system. In fact, the leading baking soda brand warns “Do not administer to children under
 28

1 age 5.” A Product that disrupts a newborn’s/infant’s digestive system cannot effectively treat the
 2 symptoms of colic. Reasonable consumers would not have purchased the Product had they known
 3 that the Product does not work for its advertised purpose. Defendant knowingly sells the Product
 4 despite having actual knowledge that it does not work.

5 6. Throughout the Class Period Defendant manufactured, sold, and distributed Parent’s
 6 Choice Gripe Water using a marketing and advertising campaign that it is an effective remedy for
 7 the signs and symptoms of colic including stomach discomfort (“discomfort” is euphemism for
 8 “pain”).

9 7. Defendant communicates the same substantive colic symptom relief message
 10 throughout its advertising and marketing of Parent’s Choice Gripe Water. Accordingly, each
 11 consumer who has purchased Parent’s Choice Gripe Water has been exposed to Defendant’s
 12 unlawful and misleading advertising.

13 8. As a direct and proximate result of Defendant’s false and misleading advertising
 14 claims and marketing practices, Defendant has caused Plaintiff and the members of the Class to
 15 purchase a falsely advertised product which does not, and cannot, perform as represented. Plaintiff
 16 and other similarly situated consumers have been harmed in the amount they paid for Parent’s
 17 Choice Gripe Water.

18 9. Plaintiff brings this action individually, and on behalf of all purchasers of Parent’s
 19 Choice Gripe Water products, to halt Defendant’s unlawful sales and marketing of these products
 20 and for violations of the California Consumer Legal Remedies Act (“CLRA”), Civil Code §§ 1750,
 21 *et seq.*, Unfair Competition Law (“UCL”), Bus. & Prof. Code §§ 17200, *et seq.*, and for unjust
 22 enrichment.

JURISDICTION AND VENUE

24 10. This Court has original jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)
 25 because this is a class action in which: (1) there are over 100 members in the proposed class; (2)
 26 members of the proposed class have a different citizenship from Defendant; and (3) the claims of
 27
 28

the proposed class members exceed \$5,000,000 in the aggregate, exclusive of interest and costs. See ECF No. 1 (Defendant's Notice of Removal).

11. This Court has personal jurisdiction over Defendant because Defendant conducts and transacts business in the State of California, contracts to supply goods within the State of California, and supplies goods within the State of California. Defendant has intentionally availed itself of the markets within California through its advertising, marketing, and sales of Parent's Choice Gripe Water to consumers, including Plaintiff. Further, Defendant has waived any personal jurisdiction challenge by responding to Plaintiff's initial complaint.

12. Venue is proper in this Court because Defendant is doing business in this County, and Plaintiff purchased Parent's Choice Gripe Water in this County.

PARTIES

13. Plaintiff Nikolas Chaplin is an individual consumer who, at all times relevant to this action, was a citizen of and resided in California. Before purchasing the Parent's Choice Gripe Water products, Plaintiff saw Defendant's representations by reading the label of Parent's Choice Gripe Water including Defendant's representations on the packaging that the Product is "Gripe Water" comparable to "Mommy's Bliss Gripe Water Original." In reliance on the claims at issue made on the label and on the belief that Parent's Choice Gripe Water was effective at reducing the symptoms of colic, Plaintiff purchased Parent's Choice Gripe Water for his child that was suffering from colicky symptoms between approximately 2019 and 2020 at Walmart retail stores in California, including in Alameda County. Relying on the Product's colic relief representations, Plaintiff paid approximately \$6 for Parent's Choice Gripe Water. Had Plaintiff known the truth—that the Product has been found to disrupt an infant's digestive system and thus, does not provide any relief from the symptoms of colic in infants—he would not have purchased the Parent's Choice Gripe Water. Plaintiff did not receive the benefit of the bargain, because Defendant's Parent's Choice Gripe Water does not and cannot improve the symptoms of colic as advertised. By purchasing the falsely advertised product, Plaintiff suffered injury-in-fact and lost money. Plaintiff continues to desire to purchase a colic relief product that actually reduces the symptoms of colic,

1 and he would purchase a colic relief product including the Product in the future if it worked as
 2 advertised. However, as a result of Defendant's ongoing false and unlawful advertising, Plaintiff
 3 will be unable to rely on the advertising when deciding in the future whether to purchase Parent's
 4 Choice Gripe Water.

5 14. Plaintiff wants to buy an effective colic-relief product and Walmart markets its
 6 Parent's Choice Gripe Water as an effective colic-relief product, so Plaintiff may buy the product
 7 in the future as currently formulated and labeled but would again be misled by the labeling and end
 8 up purchasing an ineffective product. Plaintiff currently has an infant under the age of one year.
 9 Plaintiff cannot rely on the misleading labeling and lack of disclosure of the product's
 10 ineffectiveness at treating colic.

11 15. Plaintiff Chaplin never purchased the Product on Walmart.com. Plaintiff was aware
 12 of the Mommy's Bliss product when he purchased Walmart's Gripe Water. Just like Walmart's
 13 Gripe Water, Mommy's Bliss was also advertised to treat the symptoms of colic.

14 16. Defendant Walmart Inc. is a publicly-traded Delaware corporation, with a principal
 15 place of business in Bentonville, Arkansas. Defendant manufactures, markets, and advertises and
 16 distributes Parent's Choice Gripe Water products throughout the United States, including in
 17 California. Defendant manufactured, marketed, and sold Parent's Choice Gripe Water products
 18 during the Class Period. The planning and execution of the advertising, marketing, labeling,
 19 packaging, testing, and/or business operations concerning the Parent's Choice Gripe Water were
 20 primarily carried out by Defendant.

21 17. Walmart sells the Parent's Choice Gripe Water products under the brand name
 22 "Parent's Choice" which is "Walmart's exclusive, private brand that today extends beyond infant
 23 formula."¹ Defendant markets itself as a trustworthy manufacturer of the Products: "We offer
 24 everything you need from bath time to bed time and every time in between, all with the high quality
 25 we know your little one needs."²

27 ¹ <https://www.parentschoicebaby.com/about-parents-choice.aspx> (last visited Nov. 29, 2022)
 28 ² <https://www.walmart.com/ip/Parent-s-Choice-Gripe-Water-Unflavored-4-oz/239077181>
 (last visited Nov. 29, 2022).

FACTUAL BACKGROUND

18. Defendant's Parent's Choice Gripe Water products are sold nationwide at Walmart retail chains.

19. Gripe water is commonly known as a treatment for infant stomach discomfort and the other symptoms of infantile colic.

20. Dictionary.com defines “gripe water” as “a solution given to infants to relieve colic.”³ Similarly, the online Collins Dictionary defines “gripe water” as “a solution given to infants to relieve colic,”⁴ the online MacMillan Dictionary defines “gripe water” as “a medicine for treating babies who have stomach pain,”⁵ and the online Oxford’s Learner’s Dictionaries defines “gripe water as “medicine that is given to babies when they have stomach pains.”⁶

21. The packaging of Parent's Choice Gripe Water is depicted below:

³ <https://www.dictionary.com/browse/gripe-water#:~:text=noun,to%20infants%20to%20relieve%20colic> (last visited Nov. 29, 2022).

⁴ <https://www.collinsdictionary.com/us/dictionary/english/gripe-water> (last visited Nov. 29, 2022).

⁵ https://www.macmillandictionary.com/us/dictionary/british/gripe-water (last visited Nov. 29, 2022).

⁶ https://www.oxfordlearnersdictionaries.com/us/definition/english/gripe-watertm (last visited Nov. 29, 2022).



22. As shown above, the packaging for Parent's Choice Gripe Water represents that it is Gripe Water, implying that it is an effective remedy for the symptoms of colic. The Products' packaging also refers consumers to Mommy's Bliss Gripe Water which claims that the product "relieves occasional stomach discomfort from Gas, Colic, Fussiness, Hiccups." To further reinforce that the Parent's Choice Gripe Water is an ineffective treatment for the symptoms of colic, Walmart places its Parent's Choice Gripe Water next to the Mommy's Bliss Gripe Water and other gripe water products on the shelves of Walmart retail stores.

23. Defendant also represents that the Parent's Choice Gripe Water is a safe and effective product for infants as young as 2 weeks old. The packaging states that there is a "Recommended Serving" for Infants 2 weeks to 6 months of age:

1 **DIRECTIONS:** Shake well. Slowly dispense liquid,
 2 toward side of mouth/inner cheek, using the provided
 3 dropper or syringe up to 6 times in 24-hour period.
 4 We recommend discarding 6 weeks after opening.

5 **RECOMMENDED SERVING:**

Infants 2 weeks to 1 month of age:	2.5 mL
Babies 1 to 6 months of age:	5 mL
Children 6 months and older:	10 mL
Adults:	30 mL

6 24. Defendant's Parent's Choice Gripe Water contains the following ingredients:
 7 "ORGANIC GINGER EXTRACT, ORGANIC FENNEL EXTRACT, PURIFIED WATER,
 8 VEGETABLE GLYCERIN, SODIUM BICARBONATE, CITRUS SIGFLAVONOID EXTRACT,
 9 CITRIC ACID, POTASSIUM SORBATE."⁷

10 25. Defendant's website provides evidence of the Product's intended use and the implied
 11 labeling claims. The Website advertisements are merely extrinsic evidence for the reasonable
 12 consumer standard, to contextualize how a reasonable consumer would understand the gripe water
 13 label. The Website advertisements are also evidence of the Product's implied disease claims (see
 14 below) and are admissible under the Federal Food, Drug, and Cosmetic Act to show the intended
 15 use of the Product.

16 26. On its website, Walmart represents the following directly below the Parent's Choice
 17 Gripe Water product images: "Help relieve your baby's upset tummy with Parent's Choice Original
 18 Gripe Water, 2 Weeks+. This herbal supplement solution helps treat gassiness and stomach
 19 discomfort. ... Discomfort in your little ones stomach can be frustrating and upsetting, but it's
 20 simple to treat."

21 **About this item**

22 Product details ^

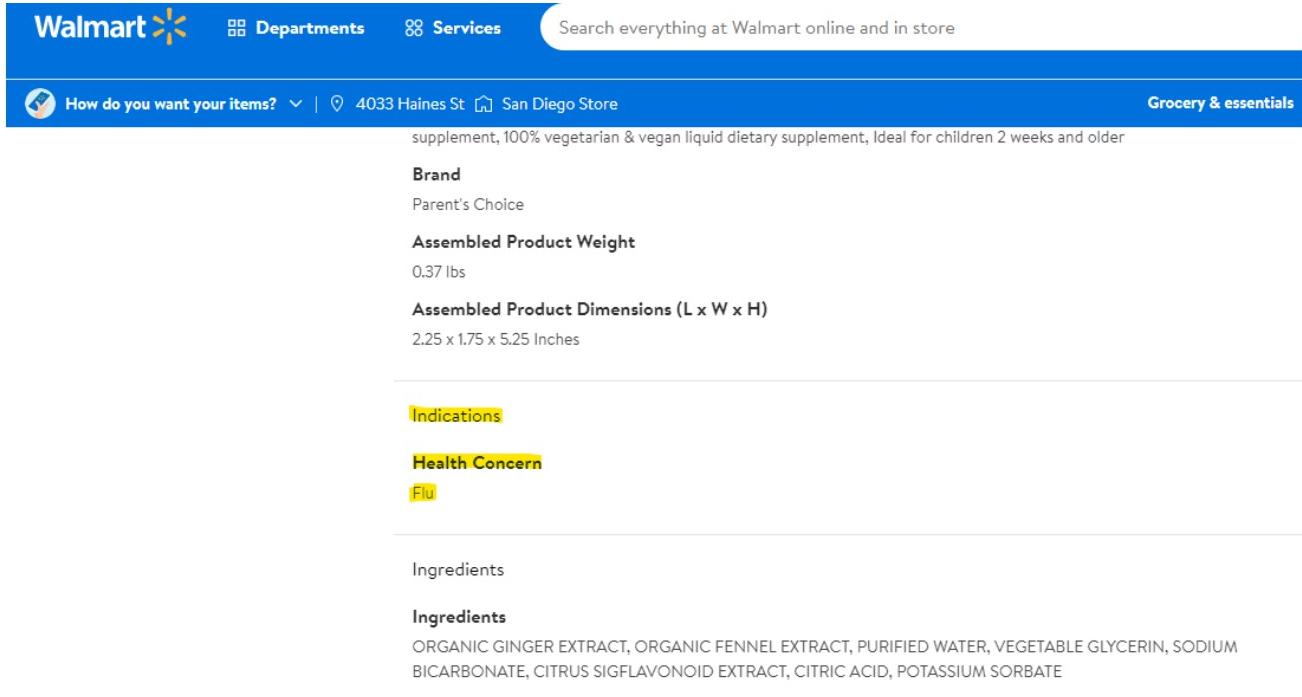
23 Herbal Supplement with Organic Ginger & Fennel Extracts, 4oz

24 Help relieve your baby's upset tummy with Parent's Choice Original Gripe Water, 2 Weeks+. This herbal supplement solution
 25 helps treat gassiness and stomach discomfort. Our 4-fluid ounce package is convenient for storing in your medicine cabinet or
 26 packing in a baby bag for on-the-go use. Discomfort in your little ones stomach can be frustrating and upsetting, but it's simple
 27 to treat. All you need to do is slowly dispense the liquid grip water towards the side of your child's inner cheek, using the
 28 provided dropper or syringe up to 6 times in a 24-hour period. Your baby will be back to their happy and playful self in no time.

Parent's Choice provides parents with baby and toddler products you need at a price that won't push your budget over the edge.
 We offer everything you need from bath time to bed time and every time in between, all with the high quality we know your
 little one needs.

1 (the “Website Claims”). A printout of Defendant’s website as of November 30, 2022, is attached
 2 hereto as **Exhibit 1**.

3 27. Defendant’s website also states that Parent’s Choice Gripe Water will treat the flu.
 4 These advertising statements are highlighted below:⁸



The screenshot shows a Walmart product page for "Parent's Choice Gripe Water Unflavored 4 oz". The page includes the Walmart logo, navigation links for Departments and Services, and a search bar. It displays the product name, a description noting it's a 100% vegetarian & vegan liquid dietary supplement for children 2 weeks and older, and details about the brand (Parent's Choice), assembled product weight (0.37 lbs), and dimensions (2.25 x 1.75 x 5.25 Inches). Below this, sections for "Indications" (highlighted in yellow) and "Health Concern" (highlighted in yellow, showing "Flu") are present. The ingredients listed are ORGANIC GINGER EXTRACT, ORGANIC FENNEL EXTRACT, PURIFIED WATER, VEGETABLE GLYCERIN, SODIUM BICARBONATE, CITRUS SIGFLAVONOID EXTRACT, CITRIC ACID, and POTASSIUM SORBATE.

17 28. The labeling and Website Claims violate federal and state law because they imply, as
 18 Walmart intends, that the Products are capable of treating the symptoms of disease. The FDA
 19 considers colic relief claims to be disease claims which require premarket drug approval. On its
 20 Website, Walmart admits that “similar items” to the Parent’s Choice Gripe Water are FDA approved
 21 medications such as Parent’s Choice Baby Cough Syrup and Parent’s Choice Infant Pain & Fever
 22 Acetaminophen:⁹

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 27 ⁸ <https://www.walmart.com/ip/Parent-s-Choice-Gripe-Water-Unflavored-4-oz/239077181>
 28 (screen shot taken on Nov. 22, 2022)

29 ⁹ <https://www.walmart.com/ip/Parent-s-Choice-Gripe-Water-Unflavored-4-oz/239077181>
 (screen shot taken on Nov. 22, 2022)

1 **Similar items you might like**

2 Based on what customers bought

3 100+ bought since yesterday

4 100+ bought since yesterday

5 100+ bought since yesterday

6 500+ bought since yesterday



7 + Add



8 + Add



9 + Add



10 + Add

11 \$5.12 \$2.56/fl oz

12 Parent's Choice Baby Cough Syrup, 2 fl. oz.

13 ★★★★☆ 12

14 Pickup Delivery

15 2-day shipping

16 Sponsored

17 \$10.12 \$2.02/fl oz

18 Xyzal Children's Allergy 24HR Oral Solution (5 Oz),...

19 ★★★★★ 157

20 Pickup Delivery

21 1-day shipping

22 Sponsored

23 \$7.97 \$1.99/fl oz

24 Genexa Children's Acetaminophen Oral Suspension, 4 oz

25 ★★★★★ 3081

26 Pickup Delivery

27 3+ day shipping

28 \$3.94 \$1.97/fl oz

29 Parent's Choice Infants' Pain and Fever, Dye-Free, Grape, 2 Fl...

30 ★★★★★ 45

31 Pickup Delivery

32 3+ day shipping

33 29. The ingredients in Parent's Choice Gripe Water have been shown to not provide relief from the symptoms of colic in infants including stomach discomfort.¹⁰ The scientific community **recommends against** the use of gripe water in children and does not recommend any of the ingredients in Parent's Choice Gripe Water for use in colicky infants because they do not work. The ingredients in Parent's Choice Gripe Water are not effective at providing any of the advertised benefits. Further, Defendant does not disclose that the sodium bicarbonate in the Products disrupts a newborn's/infant's digestive system, and thus, does not help with the symptoms of colic.

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1 **DEFENDANT'S FALSE, MISLEADING, AND UNLAWFUL ADVERTISING**

2 *Defendant's False and Misleading Advertising: Sodium Bicarbonate Is Proven Ineffective*
 3 *Because It Can Only Disrupt a Newborn's/infant's Digestive System*

4 30. The Parent's Choice Gripe Water products contain sodium bicarbonate which is more
 5 commonly known as baking soda.

6 31. Material Safety Data Sheets state that sodium bicarbonate disrupts a
 7 newborn's/infant's digestive system: "May be harmful if swallowed." "Harmful if swallowed," and
 8 "IF SWALLOWED" "Immediately call poison center or doctor. DO NOT induce vomiting."¹¹ The
 9 "Potential Health Effects" of sodium bicarbonate include "Causes gastrointestinal tract irritation."¹²

10 32. The National Capital Poison Center states that use of "baking soda as a homemade
 11 antacid can cause rapid formation of gas in the stomach. You should not use baking soda to treat
 12 stomach upset without specific direction from your healthcare provider. Stomach ruptures can occur
 13 with baking soda use after alcohol binging or a large meal. For these reasons, it is better to use over-
 14 the-counter antacid products such as calcium carbonate (like Tums®), which work in a similar way
 15 but are much safer."¹³ It also states that if baking soda is swallowed, Poison Control should be
 16 called.

17 33. The leading baking soda brand, Arm & Hammer, states on the packaging "Do not
 18 administer to children under age 5" and "KEEP OUT OF REACH OF CHILDREN
 19 If swallowed, get medical help or contact a Poison Control Center right away."¹⁴

20 34. Numerous published reports have found that sodium bicarbonate disrupts a
 21 newborn's/infant's digestive system and does not help with the symptoms of colic. An infant
 22 developed proteinuria (high levels of protein in urine) caused by the addition of sodium bicarbonate

24
 25 ¹¹ See

26 https://files.dep.state.pa.us/OilGas/BOGM/BOGMPortalFiles/IndustryResources/InformationalResources/HDD_Safety_Data_Sheets/Sodium_Bicarbonate_SDS.pdf.

27 ¹² <https://fscimage.fishersci.com/msds/20970.htm> (last visited Nov. 30, 2022).

28 ¹³ <https://www.poison.org/articles/baking-soda> (last visited Nov. 30, 2022).

¹⁴ <https://fda.report/DailyMed/b70f52eb-e3a6-4b08-b38b-8855f736ed65> (last visited Nov. 30, 2022)

to infant formula.¹⁵ In a report titled *Baking soda: a potentially fatal home remedy*, an infant was administered baking soda to “help the baby burp.” The authors reported that an infant developed “life-threatening complication” after consuming sodium bicarbonate and concluded that several case reports have been published which “emphasizes the need for warnings on baking soda products.”¹⁶

35. Al-abri and Kearny (2014) conducted a retrospective systematic review of all symptomatic cases from 2000 to 2012 involving sodium bicarbonate. One hundred ninety-two cases were identified. The authors concluded that the “baking soda can result in serious electrolyte and acid/base imbalances.”¹⁷ The study also noted that since 1990 the printed instructions for the leading baking soda product “were modified to advise against administering the product to children under age 5 years, because of reported seizure and respiratory depression in children.” In one case, a dose of 1-3 tbs of baking soda was shown to be completely ineffective at treating colic as it was associated with a death of a child and was reported by the National Poison Data System. In several cases, the use of baking soda was reported to be ineffective at treating colic because it caused significant electrolyte and acid-base abnormalities including alkalosis, hypernatremia, hypokalemia, hypochloremia and hypocalcaemia. The authors issued a stern warning to not use baking soda in infants and newborns: “healthcare providers should warn parents against using baking soda as an antacid in younger children. We also found further evidence that use of baking soda in children may be a common practice by the public after reviewing and noting several information calls to the California Poison Control System regarding from parents contemplating its use for their children.”

36. Even Walmart's gripe water competitors explain that sodium bicarbonate causes an imbalance in an infant's electrolytes:

Sodium Bicarbonate (a.k.a. Baking Soda). Sodium bicarbonate is an alkali (antacid) which alters the naturally occurring pH of a baby's stomach acid. It may counteract

¹⁵ Wechsler D et al. Apparent Proteinuria as a Consequence of Sodium Bicarbonate Ingestion. Pediatrics. 1990;86(2):318-319.

¹⁶ Nichols MH et al. Baking Soda: a potentially fatal home remedy. Pediatr Emerg Care. 1995;11(2):109-111.

¹⁷ Al-Abri SA, Kearney T. Baking soda misuse as a home remedy: case experience of the California Poison Control System. J Clin Pharm Ther. 2014 Feb;39(1):73-7.

some discomfort caused by natural acidity in a baby's tummy. However, stomach acid serves a useful purpose because it helps the body digest food and protects the gut from infections. Disrupting the stomach's natural acidity has led to concerns about risk for infection and malabsorption of nutrients like calcium, magnesium, B12, and iron. For this reason, sodium bicarbonate-containing products are not to be consumed by "children under 5 years of age", as stated clearly on antacid and baking soda boxes. Antacids always warn against extended use: "Do not use for more than 2 weeks." According to some doctors, sodium bicarbonate can cause an imbalance in babies' electrolytes, which can also lead to serious problems. Please note that antacids do interact with or prevent the absorption of many medications. According to Medline Plus, a service of the National Library of Medicine, antacids (e.g. sodium bicarbonate) "should not be given to young children (up to 6 years of age) unless prescribed by their doctor." Since children often cannot describe their symptoms well, doctor visits are advisable before giving any antacids to children. The condition may require other treatment. In such cases, not only will antacids not help, they may actually lead to unwanted side effects and/ or worsening of condition. Medline also warns against taking large doses of sodium bicarbonate with large amounts of milk or milk products. To do so may increase the chance of side effects.¹⁸

37. Medical News Today states that "a parent or caregiver should not give baking soda or any medications containing sodium bicarbonate to a child" because it does not work—"is not safe."¹⁹

38. Drs. Brown, Whaley, and Arnold published an article titled "Acute Bicarbonate Intoxication from a Folk Remedy." An infant that was in good health was given sodium bicarbonate as a cold remedy which resulted in hypernatremia, an acute metabolic alkalosis, and apnea—that is, it did not work. The authors issued a public warning that baking soda disrupts a newborn's/infant's digestive system: "The use in infants of home remedies containing bicarbonate should be discouraged."²⁰

39. An article published in *Emergency Nurse* similarly found that sodium bicarbonate disrupts a newborn's/infant's digestive system as it "can cause hypernatraemia and other metabolic disturbances."²¹ The article noted that "poisoning has occurred after use of sodium bicarbonate as

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https://www.coliccalm.com/baby_infant_newborn_articles/baby_colic_treatment.htm#SodiumBicarb (last visited Nov. 30, 2022).

¹⁹ <https://www.medicalnewstoday.com/articles/dangers-of-drinking-baking-soda#benefits> (last visited Nov. 30, 2022).

²⁰ Brown A.L. et al. Acute Bicarbonate Intoxication From a Folk Remedy. Am. J. Dis. Child. 1981;135:965.

²¹ Bates N. Poisoning: Sodium Chloride and sodium bicarbonate. Emergency Nurse. 2003;11(2):33-37.

1 a remedy for gastrointestinal” symptoms in infants.

2 40. Defendant’s Parent’s Choice Gripe Water disrupts a newborn’s/infant’s digestive
3 system. Despite this evidence, Defendant promotes the use of the Product as a treatment for infants
4 as young as two weeks old. Defendant does not disclose that its Gripe Water does not work because
5 it disrupts a newborn’s/infant’s digestive system.

6 ***Defendant’s False and Misleading Advertising: Walmart’s Gripe Water is Shown to Be***
7 ***Ineffective at Treating the Symptoms of Colic in Newborns & Infants***

8 41. Gripe water products were originally developed to treat the symptoms of malaria
9 during the 1800s and originally contained a mixture of baking soda, alcohol, and herbs. Gripe water
10 was thought to help calm a fussy baby. However, any perceived benefit was due to the presence of
11 alcohol. Modern formulations of gripe water do not contain alcohol and often do not contain baking
12 soda. However, that does not stop companies, like Defendant, from seeking to capitalize from name
13 recognition of gripe water.

14 42. Infants do not need or require the ingredients in Parent’s Choice Gripe Water. There
15 is no required daily intake for any of the ingredients in Parent’s Choice Gripe Water—the Centers
16 for Disease Control and Prevention (CDC) states that a child only needs essential vitamins and
17 minerals such as Vitamin D, iron, and zinc to grow healthy and strong.²² An infant’s digestive
18 system does not need any of the ingredients in Parent’s Choice Gripe Water because the digestive
19 system maintains homeostasis on its own along with the breast milk/formula consumed.
20 Consequently, if a substance such as Parent’s Choice Gripe Water disrupted this homeostasis,
21 disease and/or increased bacteria, allergies, and intestinal irritation would result.

22 43. The scientific community has advised against the use of gripe water for good reason—
23 “newborn infants should not be given food or drink other than breast milk, unless medically
24 indicated.”²³

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27 ²² See <https://www.cdc.gov/nutrition/infantandtoddlernutrition/vitamins-minerals/index.html>
28 (last visited Nov. 18, 2022).

29 ²³ Adhisivam B. Is gripe water baby-friendly? J. Pharmacol. Pharmacother. 212
30 Apr;3(2):207-8.

1 44. The scientific community cautions that use of gripe water products like Parent's
 2 Choice Gripe Water is an "irrational practice" which increases the risk of increased bacteria,
 3 allergies, and intestinal irritation.²⁴ Health Link, a health information service in Canada, also warns
 4 new parents: "Do not use unapproved, unproven, or potentially dangerous substances or methods as
 5 treatment for your baby who has colic."²⁵ The World Health Organization specifically recommends
 6 that mothers should exclusively breastfeed infants for optimal health.²⁶ The Canadian Paediatric
 7 Society likewise warns "Talk to your doctor before using over-the-counter or 'natural' products for
 8 colic. There is very little scientific evidence to show that these products help."²⁷

9 45. Accordingly, the scientific community has stated that gripe water advertising "need[s]
 10 to be curbed and we should ensure that no promotion for infant foods or drinks other than breast
 11 milk is done ... doctors should stop prescribing these ... medications and laws should be made
 12 stringent to prevent over the counter access of the same."²⁸

13 46. Evidence-based professional and national recommendations for the treatment of
 14 infant gastrointestinal issues recommend against the use of gripe water, herbal supplements, or any
 15 of the ingredients in Parent's Choice Gripe Water.

16 47. The American Academy of Family Physicians (AAFP) does not recommend the use
 17 of gripe water and herbal supplements including herbal ingredients such as fennel, chamomile,
 18 lemon balm.²⁹ The AAFP warns that the use of herbal products should not be administered as a
 19 treatment for infantile colic: "parents should be cautioned about their use."³⁰ The AAFP also notes
 20 that use of herbal products can create a "potential interference with normal feeding."

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 22 ²⁴ *Id.*
 23 ²⁵ <https://www.healthlinkbc.ca/pregnancy-parenting/parenting-babies-0-12-months/baby-health/colic-harmful-treatments> (last visited Nov. 30, 2022).

24 ²⁶ Vallenás C, Savage F. *Evidence for the ten steps to successful breastfeeding*. Geneva:
 25 World Health Organization/CHD/98.9; 1998. pp. 48–61.
 26 ²⁷ https://caringforkids.cps.ca/handouts/pregnancy-and-babies/colic_and_crying (last visited Nov. 9, 2022)

27 ²⁸ Adhisivam B. Is gripe water baby-friendly? *J. Pharmacol. Pharmacother.* 2012
 28 Apr;3(2):207-8.

29 ²⁹ Johnson J.D. et al. Infantile colic: recognition and treatment. *American Family Physician*.
 28 2015;92(7):577-582.

³⁰ Roberts D.M. et al. Infantile Colic. *American Family Physician*. 2004;70(4):735-740.

1 48. Ellwood et al. (2020) performed a systematic review of the available guidelines for
 2 the treatment of infantile colic which was published in the *British Medical Journal*.³¹ The aim of
 3 the study was to compare meta-data from different systematic review and national treatments
 4 guidelines for infantile colic on common outcomes. The authors specifically assessed the
 5 effectiveness of several treatment modalities on colic symptoms including infant crying time, sleep
 6 distress and adverse events. The authors note the herbal mixtures “may be harmful because herbal
 7 mixtures may affect optimal milk consumption.” The analysis found that “herbal supplements (e.g.,
 8 fennel)” are “non-recommended interventions” by The National Institute for Health and Care
 9 Excellence (NICE) on two separate occasions (2015 and 2017). Similarly, gripe water products were
 10 reported as a “non-recommended intervention” by American Academy of Family Physicians.

11 49. The National Institutes of Health (NIH) “Colic and crying – self-care” guide does not
 12 recommend the use of gripe water or any other herbal supplements.³² Instead, the NIH recommends
 13 several techniques to comfort and calm an infant.

14 50. The National Health Service (NHS), the publicly funded healthcare system in
 15 England, recently published evidence-based treatment guidelines titled *Managing Colic in Infants*
 16 *Pathway*.³³ The NHS has a “Do not recommend” rating for herbal supplements like Parent’s Choice
 17 Gripe Water.

18 51. The Royal Children’s Hospital (RCH) published evidence-based clinical practice
 19 guidelines for unsettled or crying babies in 2019. The guideline has been endorsed by the Paediatric
 20 Improvement Collaborative and specifically does not recommend “colic mixtures (e.g., gripe water)
 21 – no proven benefit.”³⁴

22 52. The British Journal of Family Medicine (BJFM) has published treatment guidelines
 23 for infantile colic. The BJFM guidelines “do not support the[] use” of herbal remedies.³⁵

24 ³¹ Ellwood J. et al. Comparison of common interventions for the treatment of infantile colic:
 25 a systematic review of reviews and guidelines. *BMJ Open*. 2020;10e035405.

26 ³² See MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US) available
 27 at <https://medlineplus.gov/ency/patientinstructions/000753.htm> (last visited Nov. 9, 2022).

28 ³³ NHS. *Managing Colic in Infants Pathway* (September 2022).

29 ³⁴ https://www.rch.org.au/clinicalguide/guideline_index/Crying_Baby_Infant_Distress/ (last
 30 visited Nov. 9, 2022).

31 ³⁵ Wall A. and Bogle V. Spotlight: infantile colic. *BJFM*. 2018;6(4).

1 53. Mount Sinai's Health Library warns "DO NOT give ginger to children under 2."³⁶
 2 For fennel (*Foeniculum vulgare*), Mount Sinai states "DO NOT give these herbs to your child on
 3 your own."³⁷

4 54. Biagioli and colleagues published a systematic review to assess the effectiveness and
 5 safety of agents for reducing colic in infants younger than four months of age. The authors utilized
 6 the standard methodological procedures of The Cochrane Collaboration. The "Authors conclusions"
 7 were "available evidence shows that herbal agents, sugar, ... cannot be recommended for infants
 8 with colic."³⁸

9 55. In 2019, peer-reviewed treatment guidelines were published which found that "Herbal
 10 remedies should not be given as there are potential risks of side effects, which may interfere with
 11 the infant's feeding."³⁹ Instead, the guidelines recommend parental reassurance and an allergen-
 12 restricted diet for mothers with a history of food intolerance or allergies.

13 56. Zhang et al. (2015) conducted a comprehensive study using data from the Infant
 14 Feeding Practices Study II, a longitudinal survey of women studied from pregnancy through the
 15 infant's first year. This was the first study to examine the prevalence of dietary botanical supplement
 16 use among US infants. The authors concluded that "many supplements and teas used were marketed
 17 and sold specifically for infants" and warn others that "supplements given to infants may pose health
 18 risks, health care providers need to recognize that infants under their care may be receiving
 19 supplements or teas."⁴⁰

20 57. Jain et al. (2015)⁴¹ published a cross-sectional study examining 335 mothers of
 21 infants. The authors concluded that gripe water "administration is a common problem in infants and

23 ³⁶ <https://www.mountsinai.org/health-library/herb/ginger> (last visited No. 29, 2022).

24 ³⁷ <https://www.mountsinai.org/health-library/condition/infantile-colic> (last visited No. 29,
 25 2022).

26 ³⁸ Biagioli_E, Tarasco_V, Lingua_C, Moja_L, Savino_F. Pain-relieving agents for infantile
 27 colic. Cochrane Database of Systematic Reviews 2016;9(CD009999).

28 ³⁹ Lam T.M.L et al. Approach to infantile colic in primary care. Singapore Med J.
 2019;60(1):12-16.

27 ⁴⁰ Zhang Y. et al. Feeding of Dietary Botanical Supplements and Teas to Infants in the
 28 United States. Pediatrics. 2015;127(6):1060-1066.

29 ⁴¹ Jain K. et al. Gripe water administration in Infants 1-6 months of age - a cross-sectional
 30 study. Clin Diagn Res. 2015 Nov;9(11):SC06-8.

1 remains a significant challenge that thwarts exclusive breast feeding.” The authors also commented
 2 that gripe water does not prevent infantile colic and may be associated with vomiting and
 3 constipation.

4 58. Gutiérrez-Castrellón et al. (2017) performed a systematic review and network meta-
 5 analysis of clinical trials published between 1960 and 2015 for the treatment of infantile colic.
 6 Pooled interventions included in the network meta-analysis were herbal remedies, including the
 7 ingredients found in Parent’s Choice Gripe Water. The authors reported wide confidence intervals
 8 in the results with considerable heterogeneity which crossed the line of no effect. In conclusion, the
 9 authors did not recommend herbal medicine, including ingredients in Parent’s Choice Gripe Water,
 10 for colic.⁴²

11 59. Defendant’s Parent’s Choice Gripe Water does not relieve colic or the signs and
 12 symptoms of colic including gassiness and stomach discomfort in newborns or infants. A significant
 13 portion of reasonable targeted customers and the reasonable general consuming public are misled
 14 by the Product’s label.

15 ***Defendant’s Gripe Water Implied Disease Claims***

16 60. Defendant’s labeling of the Product includes implied claims that it is intended to treat
 17 the symptoms of infantile colic, including gassiness and stomach discomfort. The FDA has stated
 18 that these types of advertising claims violate federal regulations which also violate state law.⁴³

19 61. The FDA recognizes that products marketed as supplements may implicitly claim to
 20 impact a disease or the signs of symptoms of a disease. 65 Fed. Reg. 1000 (Jan. 6, 2000) (codified
 21 at 21 C.F.R. pt. 101) at 1012. Implied disease claims do not mention the name of a specific disease
 22 but refer to identifiable characteristics of a disease from which the disease itself may be inferred.
 23 *Id.* In determining whether a product is implying disease treatment or prevention, regulatory

24
 25 ⁴² Gutiérrez-Castrellón P, Indrio F, Bolio-Galvis A, et al. Efficacy of Lactobacillus reuteri
 26 DSM 17938 for infantile colic. Systematic review with network meta-analysis. Medicine.
 27 2017;96(51).

28 ⁴³ The FDA regulations at issue are incorporated into California law through the Sherman
 29 Food, Drug, and Cosmetic Law (“Sherman Law”). Health & Saf. Code § 110100. In addition to
 30 this blanket provision, the Sherman Law adopts the regulatory provisions at issue here. *See id.* at
 31 §§ 109925, 111550.

1 authorities and courts look for other evidence of intended use. 65 Fed. Reg. at 1006. This includes
 2 other advertisements such as the Website Claims, marketing studies and surveys, and Walmart's
 3 intended target audience. Any "extra-label material" can be considered in determining whether a
 4 Product is intended to be used as disease treatment or prevention. "District courts within this circuit
 5 have considered factors such as the product's advertisements, the consumer's experience with the
 6 product, and market research showing consumer's typical uses of the product." *Kroessler v. CVS*
 7 *Health Corp.*, 977 F.3d 803, 815 n.9 (9th Cir. 2020)

8 62. Walmart's Gripe Water is alleged to be an unapproved drug under the FDCA and
 9 California's Sherman Law, because it is advertised with implied claims that it is intended to treat
 10 the symptoms of infantile colic, including gassiness and stomach discomfort. This violates 21
 11 U.S.C. §§ 343(r)(6), 21 C.F.R §101.93(g)(2), and Cal. Health & Saf. Code §§ 110100, 111550. To
 12 determine where a statement is an implied disease claim, the FDA first looks to the "actual label on
 13 the supplement" and then looks to "extra-label material." Here, the Website Claims reveal
 14 Walmart's intended message of its "Gripe Water" and "Compare to Mommy's Bliss" labeling
 15 message—that the product is intended to treat the symptoms of colic.

16 63. 21 U.S.C. §§ 343(r)(6) states that a dietary supplement "may not claim to diagnose,
 17 mitigate, treat, cure, or prevent a specific disease or class of diseases." To be a dietary supplement
 18 that claims to have an effect on the function of the body (here, colic symptom relief), the Product
 19 must have the FDA disclaimer "This statement has not been evaluated by the Food and Drug
 20 Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
 21 Defendant does not print this statement on its label. To be a dietary supplement, the Product that
 22 claims to have an effect on the function of the body (here, colic symptom relief), "the manufacturer
 23 shall notify the Secretary no later than 30 days after the first marketing of the dietary supplement
 24 with such statement that such a statement is being made." Defendant never sent this notification.
 25 These facts alone make Defendant's Gripe Water an illegal product. These facts show that the
 26 Product is not a "food" and is not shielded by any GRAS status (see also below).

27
 28

1 64. 21 C.F.R §101.93(g)(2) states that a dietary supplement cannot “impl[y] disease
 2 prevention or treatment.” Under 21 C.F.R §101.93(g)(2), a dietary supplement cannot “implicitly”
 3 claim to “diagnose, mitigate, treat, cure, or prevent disease,” or “implicitly” claim to have “an effect
 4 on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or
 5 lay terminology.” As described herein, the FDA and courts look at all extra-label evidence to
 6 determine whether a Product is intended to treat or prevent disease symptoms.

7 65. Advertising which implies a product has “an effect on the characteristic signs or
 8 symptoms” of a disease is considered a drug which requires FDA pre-market approval. 21 CFR
 9 101.93. Implication that a product can treat a disease’s “characteristic signs or symptoms” (without
 10 referring to the disease itself) is an unlawful disease claim. *Kroessler v. CVS Health Corp.*, 977 F.3d
 11 803, 809 (9th Cir. 2020). “The name of the product” can imply disease prevention/treatment. 21
 12 C.F.R. § 101.93(g)(2)(iv)(A).

13 66. Here, Walmart’s Gripe Water is intended to treat the signs and symptoms of colic
 14 which are the symptoms of disease according to the FDA. The FDA has stated a product that implies
 15 “colic relief” or “helps soother fussiness and crying in colicky babies” “is intended for use as drug
 16 within the meaning of 21 U.S.C. 321(g)(1)(B)” and requires premarket drug status approval. (see
 17 below and **Exhibits 3-6** attached).

18 67. Infantile colic refers to a widespread clinical disease condition in infants that causes
 19 inconsolable crying, fussing, hiccups, stomach discomfort, and irritability. These symptoms range
 20 from being benign to life-threatening.⁴⁴ The only proven treatment of colic is dicyclomine
 21 hydrochloride, an anticholinergic drug. Because there is a “drug” for treating colic, Walmart’s Gripe
 22 Water is can also considered to be a drug as it is intended to treat and prevent the same symptoms
 23 as an approved drug. This has not stopped companies like Defendant from exploiting struggling
 24 parents seeking to calm their newborns exhibiting prolonged periods of distress.

25 68. Defendant’s Gripe Water is the perfect scam because infantile colic typically subsides
 26 by the age of 4-5 months. Thus, consumers using Walmart’s Gripe Water may incorrectly think the
 27

28 ⁴⁴ Savino F & Tarasco V, New treatments for infant colic. Current Opinion in Pediatrics.
 2010;22:000-000.

1 Gripe Water had an effect on the colic symptoms although it has done nothing to actually help the
 2 infant's symptoms, and, in fact, makes them worse.

3 69. Infantile colic is known to have a significant impact on infants and their families.
 4 Defendant takes advantage of these desperate parents by unlawfully advertising its Parent's Choice
 5 Gripe Water as a treatment for colic and its symptoms. The FDA has publicly warned that claims
 6 of colic relief classify the product as an unapproved drug which may result in fines, up to one year
 7 in jail, a permanent or temporary injunction, or seizure. *See* 21 U.S.C. §§ 332-334.

8 70. The Product's packaging states that it is "Gripe Water." Defendant uses the term
 9 "Gripe Water" because it is a well-known name for products that are intended to treat the symptoms
 10 of infantile colic and implies that the Product can treat stomach discomfort, gassiness, and the other
 11 symptoms of infantile colic. The Product's packaging also states "COMPARE TO MOMMY'S
 12 BLISS® GRIPE WATER." The labeling of the Mommy's Bliss Gripe Water products states that it
 13 "relieves occasional stomach discomfort from Gas, Colic, Fussiness, Hiccups." To further reinforce
 14 that the Parent's Choice Gripe Water is an effective treatment for the symptoms of colic, Defendant
 15 places its Parent's Choice Gripe Water next to the Mommy's Bliss Gripe Water and other gripe
 16 water products on the shelves of Walmart retail stores. The Website Claims accompany the
 17 packaging and form a textual relationship with the Parent's Choice Gripe Water labeling. The
 18 Website Claims state that the Product will "relieve you baby's upset tummy," that it is for ages "2
 19 Weeks+," that it "helps treat gassiness and stomach discomfort," that the Product can be stored "in
 20 your medicine cabinet," and that "discomfort in your little ones stomach can be frustrating and
 21 upsetting, but it's simple to treat. All you need to do is slowly dispense the liquid grip water towards
 22 the side of your child's inner cheek, using the provided dropper or syringe up to 6 times in a 24-hour
 23 period. Your baby will be back to their happy and playful self in no time." The Website Claims
 24 reveal that Walmart intends that its Gripe Water be used to treat the signs and symptoms of disease
 25 as the Website Claims state the Product's "Indications" and "Health Concern" is the "flu."

1 71. In April 2020, the FDA stated that an advertising claim of “Colic Relief” is a claim
 2 that the product is intended for use as a drug and directed the company to contact the FDA’s Center
 3 for Drug Evaluation and Research.⁴⁵ (highlighted in **Exhibit 3**).
 4

5 72. In June 2021, the FDA stated that a product advertised as “Helps soothe fussiness and
 6 crying in colicky babies” and “to reduce fussiness (crying) associated with colic” were unapproved
 7 drug claims because “a number of colicky infants have serious medical conditions[.]”⁴⁶ (highlighted
 in **Exhibit 4**).
 8

9 73. In March 2018, the FDA found that a “Gripe Water” product advertised as “May aid
 10 on occasion your baby’s problems with . . . cramping . . .” established that the product was a drug
 11 under 21 U.S.C. § 321(g)(1)(B) because it was “intended for use in the cure, mitigation, treatment,
 12 or prevention of disease. . . introducing or delivering these products for introduction into interstate
 commerce for such uses violates the Act.”⁴⁷ (highlighted in **Exhibit 5** at pages 5-6).
 13

14 74. On March 19, 2021, the FDA found that a “Gripe Water” product which was
 15 advertised on a promotional website with claims that the Gripe Water product “Gives instant relief
 16 to infants and babies . . . due to grieve,” “Relieve stomach pain caused by acidity and indigestion” and
 “Gentle antacid...” was an unapproved new drug.⁴⁸ (highlighted in **Exhibit 6**).
 17
 18
 19
 20

21 ⁴⁵ FDA Warning Letter to Proctor & Gamble Company, dated April 10, 2020, available via
 22 search function at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>.
 23

24 ⁴⁶ FDA Warning Letter to SmartyPants Vitamins, dated June 28, 2021, available via search
 25 function at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>.
 26

27 ⁴⁷ FDA Warning Letter to Ozark Country Herbs, dated March 30, 2018, available at
 28 <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/ozark-country-herbs-542508-03302018> (last visited Nov. 9, 2022).
 29

30 ⁴⁸ **Exhibit 6** is a notice printed from
 31 https://www.accessdata.fda.gov/cms_ia/importalert_190.html (last visited Nov. 29, 2022) which is
 32 an FDA website which contains a compilation of a list of imported unapproved drugs. As a
 33 website printout consists of hundred of pages, Plaintiff provides only the relevant portions in
Exhibit 6.
 34

1 75. Similarly, Kaiser Permanente's health encyclopedia states that gripe water is a
 2 "potentially dangerous treatment" for colic and that "companies sell gripe water in the United States
 3 as a dietary supplement, instead of a medicine, bypassing FDA regulation."⁴⁹

4 76. Defendant did not provide the required Parent's Choice Gripe Water advertising to
 5 the FDA within the 30-day period which is required by federal law. I search for the Product on
 6 regulations.gov returned no results. Further, there is no FDA disclaimer on the labeling which is
 7 required by federal law.

8 ***Plaintiff's Allegations Are Not Preempted***

9 77. Defendant's advertising constitutes violations of federal and state law. These
 10 allegations are not preempted because they do not seek to impose labeling "that is not identical to
 11 the requirement of section 343(r)." 21 U.S.C. § 343-1(a)(5).

12 78. Plaintiff's unlawful implied disease allegations are not preempted because they are
 13 consistent with FDCA regulations. *Kroessler v. CVS Health Corp.*, 977 F.3d 803, 817 (9th Cir.
 14 2020). Plaintiff's allegations that the Product can disrupt the digestive system of a newborn/infant
 15 is not a claim that the product is dangerous or unsafe. This allegation merely supports the allegation
 16 that the Product is not effective at relieving colic symptoms.

17 79. The FDA states that baking soda is "generally recognized as safe" ("GRAS") as a
 18 food ingredient. Plaintiff is not alleging that the Product is harmful or unsafe. Plaintiff alleges the
 19 Product is ineffective because it disrupts the digestive system of a newborn/infant. GRAS laws do
 20 not state baking soda is an effective remedy for newborn's/infant's experiencing the symptoms of
 21 colic.

22 80. GRAS status also does not apply if the if the Product that contains baking soda is
 23 labeled or advertised in such a way that the labeling or advertising "may lead to deception of the
 24 consumer" or if the labeling or advertising (including any implied claims) violates the Federal Food,
 25 Drug, and Cosmetic Act ("FDCA"). 21 C.F.R. § 184.1(c).

27 28 ⁴⁹ <https://healthy.kaiserpermanente.org/health-wellness/health-encyclopedia/he.colic-harmful-treatments.hw31230> (last visited Nov. 29, 2022).

1 81. As described herein, the Product’s implied advertising message violates the FDCA
 2 because it is misleading and implies disease prevention and treatment. Thus, the GRAS status is not
 3 applicable and is not a preemption defense.

4 82. Further, GRAS status only applies to “a component of food . . . under the conditions
 5 of its intended use.” 21 C.F.R. § 170.35. Here, baking soda is not GRAS for disease treatment or
 6 prevention.

7 83. Defendant’s Product is not approved by the FDA or any other regulatory agency for
 8 use in newborns and infants experiencing the symptoms of colic. Walmart also fails to comply with
 9 over-the-counter drug regulations for antacids and, thus, is not a legal over-the-counter antacid (*see*
 10 by 21 C.F.R. §§ 201.66(c), 331, § 331.11(k)(1)).

11 84. Walmart’s Gripe Water is not a food and, instead, is advertised by Walmart as a
 12 medicine to treat infants and newborns suffering from the symptoms of colic. The intended use of
 13 the product has not been approved by the FDA, and the evidence has found that baking soda (along
 14 with the herbal ingredients in Walmart’s Gripe Water) is ineffective and can only disrupt an infant’s
 15 and newborn’s digestive system. A Product that disrupts the digestive system does not help with the
 16 symptoms of colic.

17 THE IMPACT OF DEFENDANT’S WRONGFUL CONDUCT

18 85. Defendant has ignored California law, federal regulations, and the scientific evidence
 19 demonstrating Parent’s Choice Gripe Water ineffectiveness. It has conveyed and continues to
 20 convey that Parent’s Choice Gripe Water is a “dietary supplement” (it is not because Defendant
 21 does not comply with the regulations) capable of benefiting the symptoms of colic (it does not).

22 86. As the manufacturer and distributor of Parent’s Choice Gripe Water, Defendant
 23 possesses specialized knowledge regarding its content and effects of its ingredients, and Defendant
 24 is in a superior position to know whether Parent’s Choice Gripe Water works as advertised.

25 87. Specifically, Defendant knew, but failed to disclose, or should have known, that
 26 Parent’s Choice Gripe Water is a product that is unlawfully sold and cannot benefit the symptoms
 27 of colic.

88. Defendant knew, but failed to disclose, or should have known, that Parent's Choice Gripe Water is ineffective at relieving the symptoms of colic because the evidence-based science has determined that Parent's Choice Gripe Water does not relieve the signs and symptoms of colic.

89. Plaintiff and the Class members have been and will continue to be deceived or misled by Defendant's false and deceptive colic-relief representations.

90. Defendant's colic-relief representations and omissions were a material factor in influencing Plaintiff's and the class members' decision to purchase Parent's Choice Gripe Water. In fact, the only purpose for purchasing Parent's Choice Gripe Water is to obtain the promised colic-relief benefits. Defendant's conduct has injured Plaintiff and the class members because Parent's Choice Gripe Water does not provide the advertised benefits. Had Plaintiff and other reasonable consumers known this, they would not have purchased Parent's Choice Gripe Water or would not have paid the prices they paid. Furthermore, had Plaintiff and other reasonable consumers known that Parent's Choice Gripe Water is not a dietary supplement and cannot be legally sold, they would not have purchased Parent's Choice Gripe Water or would not have paid the prices they paid.

91. Parent's Choice Gripe Water retails for approximately \$6 per unit. Because of Defendant's unlawful, false, and deceptive advertising, Parent's Choice Gripe Water has become one of the highest-selling products in the gripe water category.

LEGAL REMEDIES ARE INADEQUATE

92. Plaintiff and members of the Class are entitled to equitable relief as no adequate remedy at law exists. The statutes of limitations for the causes of action pled herein vary. Class members who purchased the Product more than three years prior to the filing of the complaint will be barred from recovery if equitable relief were not permitted under the UCL.

93. The scope of actionable misconduct under the unfair prong of the UCL is broader than the other causes of action asserted herein. It includes Defendant's overall unfair marketing scheme to promote and brand the Product with the labeling representations, across a multitude of media platforms, including the Product's labels and packaging, over a long period of time, in order to gain an unfair advantage over competitor products. The UCL also creates a cause of action for violations

1 of law (such as statutory or regulatory requirements and court orders related to similar
 2 representations and omissions made on the type of products at issue). This is especially important
 3 here because Plaintiff alleges Defendant has committed “unlawful” acts by failing to comply with
 4 21 U.S.C. §§ 343(r)(6), 21 U.S.C. § 343(a), 21 C.F.R. § 1.21(a), 21 C.F.R. §101.93(g), 21 C.F.R. §
 5 101.93(a)-(b), and Cal. Health & Saf. Code §§ 110100, 111550 (*see also* below Count II) and brings
 6 a claim for violation of the UCL’s “unlawful prong.” No other causes of action allow this claim to
 7 proceed, and thus, there is no adequate remedy at law for this specific violation of the UCL’s
 8 unlawful prong. Plaintiff’s UCL unlawful prong claim does not rest on the same conduct as his other
 9 causes of action, and there is no adequate remedy at law for this specific claim.

10 94. Injunctive relief is appropriate on behalf of Plaintiff and members of the Class because
 11 Defendant continues to misrepresent the Products with the colic relief and other “gripe water”
 12 representations and violate federal and state regulations. Injunctive relief is necessary to prevent
 13 Defendant from continuing to engage in the unfair, fraudulent, and/or unlawful conduct described
 14 herein and to prevent future harm—none of which can be achieved through available legal remedies
 15 (such as monetary damages to compensate past harm). Injunctive relief, in the form of affirmative
 16 disclosures is necessary to dispel the public misperception about the Products that has resulted from
 17 years of Defendant’s unfair, fraudulent, and unlawful marketing efforts. Such disclosures would
 18 include, but are not limited to, publicly disseminated statements that the Products’ labeling
 19 misrepresentations are not true and providing accurate information about the Products’ true nature;
 20 and/or requiring prominent qualifications and/or disclaimers on the Products’ front label concerning
 21 the Products’ true nature. An injunction requiring affirmative disclosures to dispel the public’s
 22 misperception, and prevent the ongoing deception and repeat purchases, is also not available through
 23 a legal remedy (such as monetary damages). In addition, Plaintiff is currently unable to accurately
 24 quantify the damages caused by Defendant’s future harm, because discovery and Plaintiff’s
 25 investigation have not yet completed, rendering injunctive relief necessary. Further, because a
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public injunction is available under the UCL, and damages will not adequately benefit the general public in a manner equivalent to an injunction.

95. It is premature to determine whether an adequate remedy at law exists. This is an initial pleading and discovery has not yet commenced and/or is at its initial stages. No class has been certified yet. No expert discovery has commenced and/or completed. The completion of fact/non-expert and expert discovery, as well as the certification of this case as a class action, are necessary to finalize and determine the adequacy and availability of all remedies, including legal and equitable, for Plaintiff's individual claims and any certified class or subclass. Plaintiff therefore reserves their right to amend this complaint and/or assert additional facts that demonstrate this Court's jurisdiction to order equitable remedies where no adequate legal remedies are available for either Plaintiff and/or any certified class or subclass. Such proof, to the extent necessary, will be presented prior to the trial of any equitable claims for relief and/or the entry of an order granting equitable relief.

CLASS ACTION ALLEGATIONS

96. Plaintiff brings this class action pursuant to Federal Rules of Civil Procedure 23(b)(2) and 23(b)(3) on behalf of the following classes:

Multi-State Unjust Enrichment Class (the “Class”)

All persons who purchased Parent's Choice Gripe Water for personal use in California or other states with similar laws until the date notice is disseminated.

California Class (the “Subclass”)

All persons in California who purchased Parent's Choice Gripe Water for personal use until the date notice is disseminated.

97. Together the classes are referred to as the “Class” below. Excluded from the Class are: (i) Defendant and its officers, directors, and employees; (ii) any person who files a valid and timely request for exclusion; and (iii) judicial officers and their immediate family members and associated court staff assigned to the case.

1 98. Plaintiff reserves the right to amend or otherwise alter the class definition presented
 2 to the Court at the appropriate time, or to propose or eliminate sub-classes, in response to facts
 3 learned through discovery, legal arguments advanced by Defendant, or otherwise.

4 99. The Class is appropriate for certification because Plaintiff can prove the elements of
 5 the claims on a classwide basis using the same evidence as would be used to prove those elements
 6 in individual actions alleging the same claims.

7 100. Numerosity: Class Members are so numerous that joinder of all members is
 8 impracticable. Plaintiff believes that there are thousands of consumers who are Class Members
 9 described above who have been damaged by Defendant's deceptive and misleading practices.

10 101. Commonality and Predominance: There is a well-defined community of interest in the
 11 common questions of law and fact affecting all Class Members. The questions of law and fact
 12 common to the Class Members which predominate over any questions which may affect individual
 13 Class Members include, but are not limited to:

- 14 a. Whether Defendant is responsible for the conduct alleged herein which was uniformly
 15 directed at all consumers who purchased the Products;
- 16 b. Whether Defendant's misconduct set forth in this Complaint demonstrates that
 17 Defendant engaged in unfair, fraudulent, or unlawful business practices with
 18 respect to the advertising, marketing, and sale of the Products;
- 19 c. Whether Defendant made false and/or misleading statements concerning the Products
 20 that were likely to deceive the public;
- 21 d. Whether Plaintiff and the Class are entitled to injunctive relief;
- 22 e. Whether Plaintiff and the Class are entitled to money damages under the same causes
 23 of action as the other Class Members.

24 102. Typicality: Plaintiff is a member of the Class Plaintiff seeks to represent. Plaintiff's
 25 claims are typical of the claims of each Class Member in that every member of the Class was
 26 susceptible to the same deceptive, misleading conduct and purchased the Products. Plaintiff is
 27 entitled to relief under the same causes of action as the other Class Members.

1 103. Adequacy: Plaintiff is an adequate Class representative because Plaintiff's interests
 2 do not conflict with the interests of the Class Members Plaintiff seeks to represent; the consumer
 3 fraud claims are common to all other members of the Class, and Plaintiff has a strong interest in
 4 vindicating Plaintiff's rights; Plaintiff has retained counsel competent and experienced in complex
 5 class action litigation and Plaintiff intends to vigorously prosecute this action. Plaintiff has no
 6 interests which conflict with those of the Class. The Class Members' interests will be fairly and
 7 adequately protected by Plaintiff and proposed Class Counsel. Defendant has acted in a manner
 8 generally applicable to the Class, making relief appropriate with respect to Plaintiff and the Class
 9 Members. The prosecution of separate actions by individual Class Members would create a risk of
 10 inconsistent and varying adjudications.

11 104. Superiority: The Class is properly brought and should be maintained as a class action
 12 because a class action is superior to traditional litigation of this controversy. A class action is
 13 superior to the other available methods for the fair and efficient adjudication of this controversy
 14 because:

- 15 a. The joinder of hundreds of individual Class Members is impracticable, cumbersome,
 unduly burdensome, and a waste of judicial and/or litigation resources;
- 16 b. The individual claims of the Class Members may be relatively modest compared with
 the expense of litigating the claim, thereby making it impracticable, unduly
 burdensome, and expensive to justify individual actions;
- 17 c. When Defendant's liability has been adjudicated, all Class Members' claims can be
 determined by the Court and administered efficiently in a manner far less burdensome
 and expensive than if it were attempted through filing, discovery, and trial of all
 individual cases;
- 18 d. This class action will promote orderly, efficient, expeditious, and appropriate
 adjudication and administration of Class claims;
- 19 e. Plaintiff knows of no difficulty to be encountered in the management of this action
 that would preclude its maintenance as a class action;

- f. This class action will assure uniformity of decisions among Class Members;
- g. The Class is readily definable and prosecution of this action as a class action will eliminate the possibility of repetitious litigation; and
- h. Class Members' interests in individually controlling the prosecution of separate actions is outweighed by their interest in efficient resolution by single class action;

105. Rule 23(b)(2): In the alternative, the Class also may be certified because Defendant has acted or refused to act on grounds generally applicable to the Class thereby making final declaratory and/or injunctive relief with respect to the members of the Class as a whole, appropriate.

106. Plaintiff seeks preliminary and permanent injunctive and equitable relief on behalf of the Class, on grounds generally applicable to the Class, to enjoin and prevent Defendant from engaging in the acts described, and to require Defendant to provide full restitution to Plaintiff and Class members.

107. Unless the Class is certified, Defendant will retain monies that were taken from Plaintiff and Class members as a result of Defendant's wrongful conduct. Unless a classwide injunction is issued, Defendant will continue to commit the violations alleged and the members of the Class and the general public will continue to be misled.

108. Notice: Plaintiff and counsel anticipate that notice to the proposed Class will be effectuated through recognized, Court-approved notice dissemination methods, which may include United States mail, electronic mail, Internet postings, and/or published notice.

COUNT I

Violation of Consumer Legal Remedies Act (“CLRA”) Civil Code §§ 1750, et seq

109. Plaintiff re-alleges and incorporates by reference all allegations set forth in the preceding paragraphs as if fully set forth verbatim herein.

110. Plaintiff brings this claim individually and on behalf of the California Subclass against Defendant.

111. At all times relevant hereto, Plaintiff and members of the Class were “consumer[s],” as defined in Civil Code section 1761(d).

1 112. At all relevant times, Defendant constituted a “person,” as defined in Civil Code
 2 section 1761(c).

3 113. At all relevant times, the Products manufactured, marketed, advertised, and sold by
 4 Defendant constituted “goods,” as defined in Civil Code section 1761(a).

5 114. The purchases of the Products by Plaintiff and members of the Class were and are
 6 “transactions” within the meaning of Civil Code section 1761(e).

7 115. Defendant disseminated, or caused to be disseminated, through its advertising—
 8 including Defendant’s Website Claims that the Products are a treatment to the flu and the symptoms
 9 of colic and are lawfully sold in the United States which they are not because the Products do not
 10 provide relief from the flu, the symptoms of colic, and are illegal unapproved drugs. Defendant’s
 11 representations violate the CLRA by:

- 12 (a) Defendant represented that the Products have characteristics, ingredients, uses, and
 benefits which they do not have (Civil Code § 1770(a)(5));
- 14 (b) Defendant represented that the Products are of a particular standard, quality, or grade,
 which they are not (Civil Code § 1770(a)(7));
- 16 (c) Defendant advertised the Products with an intent not to sell the Products as advertised
 (Civil Code § 1770(a)(9)); and
- 18 (d) Defendant represented that the subject of a transaction has been supplied in
 accordance with a previous representation when it has not (Civil Code § 1770(a)(16)).

20 116. Defendant violated the CLRA because the Products do not relieve the symptoms of
 21 colic (e.g., stomach discomfort, gassiness). Defendant knew or should have known that its Products
 22 do not relieve the symptoms of colic and that the labeling is illegal.

23 117. Defendant’s actions as described herein were done with conscious disregard of
 24 Plaintiff’s rights and was wanton and malicious.

25 118. Defendant’s wrongful business practices constituted, and constitute, a continuing
 26 course of conduct in violation of the CLRA since Defendant is still representing that its Products
 27 have characteristics which they do not have.

119. Pursuant to Civil Code section 1782(d), Plaintiff and members of the Class seek an order enjoining Defendant from engaging in the methods, acts, and practices alleged herein, and for restitution and disgorgement.

120. Pursuant to Civil Code section 1782, on November 30, 2022, Plaintiff notified Defendant in writing by certified mail of the alleged violations of the CLRA and demanded that Defendant rectify the problems associated with the actions detailed above and give notice to all affected consumers of its intent to so act. Defendant has failed to rectify or agree to rectify the problems associated with the actions detailed herein and give notice to all affected consumers within 30 days of the date of written notice pursuant to § 1782 of the CLRA. Thus, Plaintiff seeks claims for actual, punitive, and statutory damages, as appropriate.

121. Pursuant to § 1780(d) of the CLRA, attached as **Exhibit 2** is an affidavit showing that this action was commenced in a proper forum.

COUNT II

Violation of Unfair Competition Law Business & Professional Code §§ 17200, et seq.

122. Plaintiff and Class Members reallege and incorporate by reference each allegation set forth above as if fully set forth herein.

123. Plaintiff brings this claim individually and on behalf of members of the California Subclass against Defendant.

124. Defendant is subject to the UCL, Bus. & Prof. Code § 17200 *et seq.* The UCL provides, in pertinent part: “Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising” The UCL also provides for injunctive relief and restitution for violations.

125. “By proscribing any unlawful business practice, § 17200 borrows violations of other laws and treats them as unlawful practices that the UCL makes independently actionable.” *Cel-Tech Communications, Inc. v. Los Angeles Cellular Telephone Co.*, 20 Cal. 4th 163, 180 (1999) (citations and internal quotation marks omitted).

126. Virtually any law or regulation—federal or state, statutory, or common law—can

1 serve as a predicate for a UCL “unlawful” violation. *Klein v. Chevron U.S.A., Inc.*, 202 Cal. App.
 2 4th 1342, 1383 (2012).

3 127. Defendant has violated the UCL’s “unlawful prong” as a result of its violations of the
 4 CLRA and numerous state and federal laws governing drugs and dietary supplements. By failing to
 5 comply federal and state regulations governing drugs and dietary supplements, Defendant has also
 6 violated 21 U.S.C. §§ 343(r)(6), 21 U.S.C. § 343(a), 21 C.F.R. § 1.21(a), 21 C.F.R. §101.93(g), 21
 7 C.F.R. § 101.93(a)-(b), and Cal. Health & Saf. Code §§ 110100, 111550.

- 8 a. 21 U.S.C. §§ 343(r)(6): Defendant violates this law because the advertising is
 9 misleading (21 U.S.C. §§ 343(r)(6)(B)), the label does not contain the FDA required
 10 disclaimer (21 U.S.C. §§ 343(r)(6)(C)), and Defendant did not send the U.S. Secretary
 11 of Health and Human Services a notice of the labeling statements within 30 days after
 12 first marketing the Product (21 U.S.C. §§ 343(r)(6)(C)).
- 13 b. 21 U.S.C. § 343(a): Defendant violates this law because the Product’s labeling is
 14 misleading which also violates “section 350(b)(2) of this title.”
- 15 c. 21 C.F.R. § 1.21(a): Defendant violates this law because the Product’s labeling is
 16 misleading as it fails to reveal facts that are (1) material in light of other representation
 17 made or suggested by statement, word, design, devise or an combination thereof; and
 18 (2) material with respect to consequences which may result from use of the Product
 19 under the condition prescribed in the labeling and conditions of use as are customary
 20 and/or usual.
- 21 d. 21 CFR §101.93(g): Defendant violates this law because, as described herein, the
 22 Product’s labeling implies the product mitigates, treats cures, or prevents disease
 23 under 21 U.S.C. § 343(r)(6).
- 24 e. 21 C.F.R. § 101.93(a): Defendant violates this law because it did not send the U.S.
 25 Secretary of Health and Human Services a notice of the labeling statements within 30
 26 days after first marketing the Product.
- 27 f. 21 C.F.R. § 101.93(b): Defendant violates this law because the Product’s label does

1 not contain the FDA required disclaimer.

- 2 g. Cal. Health & Saf. Code § 110100: Defendant violates this law because defendant
 3 violates food and dietary supplement regulations (as described above and throughout)
 4 under the Federal Food, Drug, and Cosmetic Act.
 5 h. Cal. Health & Saf. Code § 111550: Defendant violates this law because it is selling
 6 an unapproved drug as defined by the Federal Food, Drug, and Cosmetic Act and as
 7 the Federal Food, Drug, and Cosmetic Act is interpreted by case law including
 8 *Kroessler v. CVS Health Corp.*, 977 F.3d 803 (9th Cir. 2020).

9 128. Throughout the Class Period, Defendant committed acts of unfair competition, as
 10 defined by § 17200, by using unlawful and misleading statements to promote the sale of the
 11 Products, as described above.

12 129. Defendant's misrepresentations and other conduct, described herein, violated the
 13 "unfair prong" of the UCL because the conduct is substantially injurious to consumers, offends
 14 public policy, and is immoral, unethical, oppressive, and unscrupulous, as the gravity of the conduct
 15 outweighs any alleged benefits. Defendant's conduct is unfair in that the harm to Plaintiff and
 16 members of the California Subclass arising from Defendant's conduct outweighs the utility, if any,
 17 of those practices.

18 130. Defendant's practices as described herein are of no benefit to consumers who are
 19 tricked into believing that the Products will provide relief for stomach discomfort for their
 20 newborns. Defendant's practice of injecting misinformation into the marketplace about the
 21 capabilities of its Products is unethical and unscrupulous, especially because consumers trust
 22 companies like Defendant to provide accurate information about Products for newborns. Taking
 23 advantage of that trust, Defendant misrepresents the effectiveness of its Products to increase its
 24 sales. Consumers believe that Defendant is an authority on the effectiveness, safety and quality of
 25 gripe water Products for their newborns and therefore believe Defendant's representations that its
 26 Products can provide stomach relief for their newborns/infants.

27 131. Defendant's conduct described herein, violated the "fraudulent" prong of the UCL by
 28

representing that the Products were effective at providing relief related for stomach discomfort in newborns, when in fact they were not.

132. Plaintiff and members of the California Subclass are not sophisticated experts with independent knowledge of the formulations or efficacy of the Products, and they acted reasonably when they purchased the Products based on their belief that Defendant's representations were true.

133. Defendant knew or should have known, through the exercise of reasonable care, that its representations about the Products were untrue and misleading.

134. As a direct and proximate result of these acts, consumers have been and are being harmed. Plaintiff and members of the California Subclass have suffered injury and actual out of pocket losses as a result of Defendant's unfair, unlawful, and fraudulent business acts and practices because: (a) Plaintiff and members of the California Subclass would not have purchased the Products on the same terms if they had known the true facts regarding the lack of effectiveness of the Products; (b) Plaintiff and members of the California Subclass paid a price premium due to the misrepresentations of Defendant's Products; and (c) Defendant's Products did not have the quality, effectiveness, or value as promised.

135. Pursuant to California Business & Professions Code § 17203, Plaintiff and members of the California Subclass are therefore entitled to: (a) an Order requiring Defendant to cease the acts of unfair competition alleged herein; (b) full restitution of all monies paid to Defendant as a result of its deceptive practices; (c) interest at the highest rate allowable by law; and (d) the payment of Plaintiff's attorneys' fees and costs.

COUNT III

Unjust Enrichment

136. Plaintiff and Class Members reallege and incorporate by reference each allegation set forth above as if fully set forth herein.

137. Plaintiff brings this claim individually and on behalf of the members of the Class against Defendant.

138. Plaintiff and Class members conferred a benefit on Defendant by purchasing the Products and by paying a price premium for them. Defendant has knowledge of such benefits.

139. Defendant has been unjustly enriched in retaining the revenues derived from Class members' purchases of the Products, which retention under these circumstances is unjust and inequitable because Defendant misrepresented that the Products were effective in treating stomach discomfort and colic. This misrepresentation cause injuries to Plaintiff and Class Members, because they would not have purchased the Products if the true facts regarding the effectiveness of the Products were known.

140. Because Defendant's retention of the non-gratuitous benefit conferred on it by Plaintiff and Class members is unjust and inequitable, Defendant must pay restitution to Plaintiff and the Class members for their unjust enrichment, as ordered by the Court.

JURY DEMAND

141. Plaintiff demands a trial by jury on all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the Class and Subclass, requests for judgment as follows:

(a) Declaring this action to be a proper class action and certifying Plaintiff as the representative of the Class and the California Subclass, and Plaintiff's attorneys as Class Counsel to represent the Class and California Subclass members;

(b) An order declaring Defendant's conduct violates the statutes referenced herein;

(c) Entering preliminary and permanent injunctive relief against Defendant, directing Defendant to correct its practices and to comply with consumer protection statutes;

(d) Awarding damages, including treble damages

(e) Awarding punitive damages;

(f) Awarding restitution and disgorgement in the alternative to damages in an amount that is different than the amount that would be compensable for damages;

(g) Awarding Plaintiff and the Class and the California Subclass Members their costs and expenses incurred in this action, including reasonable allowance of fees for Plaintiff's attorneys and experts, and reimbursement of Plaintiff's expenses; and

(h) Granting such other and further relief as the Court may deem just and proper.

Dated: June 15, 2023

CROSNER LEGAL, P.C.

By: /s/ Craig W. Straub

Craig W. Straub

Zachary M. Crosner

Chad A. Saunders

Attorneys for Plaintiff

Attorneys for Plaintiff